Clinical Policy: **Prostatic Urethral Lift**

Reference Number: HNCA.CP.MP.537
Effective Date: 09/14
Last Review Date: 09/19

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**
The UroLift System (NeoTract Inc.) is a minimally invasive, prostatic urethral lift (PUL) system that provides anterolateral mechanical traction of the lateral lobes of the prostate, opening the urethral lumen, and reducing urinary obstruction. The system is proposed as a minimally invasive treatment of symptoms due to urinary outflow obstruction secondary to benign prostatic hyperplasia (BPH) in men age 45 and older. This policy addresses the medical necessity criteria for prostatic urethral lift.

**Policy/Criteria**
It is the policy of Health Net of California that prostatic urethral lift (i.e., UroLift System) is medically necessary for treatment of men with moderate to severe symptomatic benign prostatic hyperplasia with urinary outflow tract symptoms who meet all of the following criteria:

A. Age 45 and older
B. Refractory to or intolerant of usual medical management
C. Prostate volume <80ml
D. Median lobe of prostate is not obstructed or protruding
E. Absence of urinary tract infection, gross hematuria or urinary incontinence
F. No urethral condition that may prevent insertion of delivery system into the bladder
G. No known allergy to nickel or other metals.

**Background**
Benign prostatic hyperplasia (BPH) is an enlargement or growth of the prostate that often occurs as men age. The enlarged prostate restricts the urethra and applies pressure on the base of the bladder leading to lower urinary tract symptoms (LUTS) such as increased frequency of urination, nocturia, hesitancy, urgency, and weak urinary stream. Although LUTS secondary to BPH is not usually life-threatening, it can significantly impact the quality of life. Treatment goals include reducing symptoms, alteration of disease progression and prevention of complications that can be associated with BPH/LUTS. Symptomatic patients may benefit from medical or surgical treatment (e.g., transurethral resection of the prostate, open prostatectomy etc.)

The UroLift System, a prostatic urethral lift (PUL) system, is proposed as a minimally invasive option to treat BPH. The UroLift System is composed of two main components: the UroLift Delivery Device and UroLift Implant. The delivery device contains a preloaded implant that deploys, self-adjusts, tensions, and trims a permanent tensioning suture. The suture runs from the urethra to the outer prostatic capsule and serves to compress the lateral lobe of the prostate. Implants are delivered bilaterally to separate the encroaching lobes. Four to 5 implants are typically inserted, but this varies with the size and shape of the prostate.
Three year results of a multi-center, randomized, patient and outcome assessor blinded trial of the PUL in 206 men with bothersome LUTS due to BPH reported PUL offers rapid improvement in voiding and storage symptoms, quality of life and flow rate that is durable to 3 years. In addition, it preserved total sexual function while offering a rapid return to normal physical activities. Several other trials reported similar results, noting PUL improves LUTS and urinary flow while preserving erectile and ejaculatory function.

FDA Approval
In 2013, the NeoTract UroLift® System UL400 (NeoTract) was cleared (after receiving clearance through FDA’s de novo classification process in March 2013. In 2016, FDA determined that the UL500 was substantially equivalent to existing devices (UL400) for the treatment of symptoms of urinary flow obstruction secondary to BPH in individuals’ ages 50 years and older. In 2017, FDA expanded the indication for the UL400 and UL500 to include lateral and median lobe hyperplasia in men 45 years or older.

American Urological Association
The most current American Urological Association (AUA) guideline on the surgical management of BPH was published in 2018 noting: “Clinicians should consider PUL [prostatic urethral lift] as an option for patients with LUTS [lower urinary tract symptoms] attributed to BPH [benign prostatic hyperplasia] provided prostate volume <80g and verified absence of an obstructive middle lobe; however, patients should be informed that symptom reduction and flow rate improvement is less significant compared to TURP [transurethral resection of the prostate].”

National Institute of Health and Care Excellence (NICE)
Medical Technologies Guidance on UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia concludes that UroLift system should be considered as an alternative to current surgical procedures for use in a daycase setting in men with lower urinary tract symptoms of BPH who are aged 50 years and older and who have a prostate of less than 100 ml without an obstructing middle lobe.

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2015, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.
CPT® Codes | Description
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52441 | Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant
52442 | each additional permanent adjustable transprostatic implant

HCPCS Codes | Description
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C9739 | Cystourethroscopy, with insertion of transprostatic implant; 1 to 3 implants
C9740 | Cystourethroscopy, with insertion of transprostatic implant; 4 or more implants

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

| ICD-10-CM Code | Description |
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N40.1 | Enlarged prostate with lower urinary tract symptoms
N40.3 | Nodular prostate with lower urinary tract symptoms
N41.0-N41.9 | Inflammatory disease of prostate

Reviews, Revisions, and Approvals

| Policy adopted from Health Net NMP537 Prostatic Urethral Lift | 9/16 |
| Update no changes | 9/17 9/17 |
| Update no changes | 9/18 |
| Revised age, clarified symptoms of urinary tract outflow symptoms, updated statement by the references AUA, updated references | 9/19 9/19 |

References

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,
contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.

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